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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,340	02/06/2002	John A. Hey	CN01383K	4276

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SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
2000 GALLOPING HILL ROAD  
KENILWORTH, NJ 07033-0530

EXAMINER
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HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/072,340

Applicant(s)

HEY ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, and 14 (insofar as claim 14 is drawn to the employment of a dual H<sub>3</sub>/m<sub>2</sub> antagonist and an acetylcholinesterase inhibitor), drawn to a method of treating cognition deficit disorders using a single agent: a dual H<sub>3</sub>/m<sub>2</sub> antagonist and optionally an acetylcholinesterase inhibitor, classified in class 514, subclass 279, 317, and 319.
- II. Claims 3-9, and 14 (insofar as claim 14 is drawn to the employment of 2 different agents: an H<sub>3</sub> antagonist and an m<sub>2</sub> antagonist and an acetylcholinesterase inhibitor), drawn to a method of treating cognition deficit disorders using 2 different agents: an H<sub>3</sub> antagonist and an m<sub>2</sub> antagonist, and optionally an acetylcholinesterase inhibitor, classified in for example, class 514, subclass 317, 333, 364, 265, 219, 279, 319, and 349.
- III. Claims 10-13 and 15-16, drawn to a composition and kit comprising 1a) an H<sub>3</sub> antagonist and an m<sub>2</sub> antagonist in combination; or 1b) a dual H<sub>3</sub>/m<sub>2</sub> antagonist and 2) an acetylcholinesterase inhibitor, classified in class 514, subclass 317, 333, 364, 265, 219, 279, 319, and 349.

The inventions are distinct, each from the other because of the following reasons:

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Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different mode of operations. The invention of Group I operates by using a dual H<sub>3</sub>/m<sub>2</sub> antagonist and acetylcholinesterase inhibitor; and the invention of Group II operates by employing 2 different agents: an H<sub>3</sub> antagonist and an m<sub>2</sub> antagonist and acetylcholinesterase inhibitor. Please note that a dual H<sub>3</sub>/m<sub>2</sub> antagonist is belongs to a different pharmacological class of compounds from a single H<sub>3</sub> antagonist or m<sub>2</sub> antagonist. Therefore the search for all of the invention will impose an undue burden to the Office.

Inventions III and I-II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treating cognition deficit disorder can be practiced with a materially different product such as vitamin E and selegiline.

Claim 14 link(s) inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim14. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the

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instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. Please note that claim 14 is drawn to a method of treating cognition deficit disorder by employing either i) a dual H<sub>3</sub>/m<sub>2</sub> antagonist and an acetylcholinesterase inhibitor or ii) an H<sub>3</sub> antagonist, an m<sub>2</sub> antagonist, and an acetylcholinesterase inhibitor.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

### ***Election of Species***

Claims 1-16 are generic to a plurality of disclosed patentably distinct species comprising various species of H<sub>3</sub> antagonist, m<sub>2</sub> antagonist, and acetylcholinesterase inhibitor. These agents are classified into different classification, for example, for thioperamide, it is classified in class 514, subclass 333; for impromidine, it is classified in class 514, subclass 365, for clozapine, it is classified in class 514, subclass 219, for GR 175737, it is classified in class 514, subclass 364; for UCL 1199, it is classified in

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class 514, subclass 349; for tacrine, it is classified in class 514, subclass 279, and for donepezil, it is classified in class 514, subclass 319. Applicant is required under 35 U.S.C. 121 to elect a single disclosed acetylcholinesterase inhibitor if the invention of Group I is elected or a single disclosed combination of H<sub>3</sub> antagonist, m<sub>2</sub> antagonist, and acetylcholinesterase inhibitor if the invention of Group II or III is elected, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P. Sec. 812.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



San-ming Hui  
Patent Examiner  
Art Unit 1617  
May 5, 2003